

Appl. No. 09/596,362
Request for Reconsideration After Final

REMARKS/ARGUMENTS

Claims Rejection - 35 USC §§ 102 and 103:

In the Final Office Action mailed April 13, 2005, the Examiner reaffirmed her rejection of applicant's independent claim 1 as anticipated by Cherksey (US 5,234,947) and Umbdenstock (US 5,332,579) and independent claim 13 as anticipated by and obvious in view of Umbdenstock.

During the telephone interview held July 5, 2005, applicant explained that his invention is distinguishable over the cited prior art because applicant's invention has been shown to be effective in the treatment of alcohol craving, which is distinct from the treatment of alcohol withdrawal symptoms.

Cherksey teaches without substantiation the use of potassium channel activators to treat withdrawal symptoms. Umbdenstock makes a vague reference to kava kava as an ingredient in one of a variety of nutritional supplements claimed useful to "assist persons recovering from addiction". Neither Cherksey nor Umbdenstock teach the use of kava or kava pyrones to reduce craving in active addicts and alcoholics. The prior art does not teach the use of kava pyrones to address the craving or the addiction itself, only, if anything, the physical symptoms consequent to withdrawal and recovery.

Applicant is the first person known to have tested the use of kava pyrones on substance abusers while they were actively abusing the substance. Applicant's study, described in the specification, demonstrated that kava pyrones are effective in reducing and sometimes stopping the consumption of alcohol among active alcoholics. Applicant's data demonstrates a decrease in craving and addiction among alcoholics prior to the onset of withdrawal or recovery.

Independent claim 13 contains the element of a "non-alcoholic beverage formulated to simulate the taste and aroma of an alcoholic beverage" that is neither found, taught nor suggested in the cited prior art.

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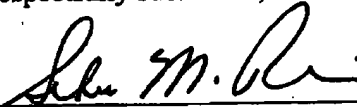
Whereas Applicant believes that independent claims 1 and 13 are distinguishable over the cited art and therefore allowable in their present form, Applicant would consider further amending claim 1 such that it reads "A method for reducing the craving for alcohol in individuals who are actively abusing alcohol by administering"

Attached to this reply and request for reconsideration is a short statement by applicant further explaining the aspects of his invention that distinguish over Cherksey and Umbdenstock.

The Examiner is invited to contact the undersigned attorney, at (808) 521-7080 business hours Hawaii standard time, or via email at <sethreiss@lawhi.com>, in order that the undersigned attorney may endeavor to resolve any outstanding issues as expeditiously as possible thereby to avoid prolonged prosecution of the present application.

This paper is being faxed within **three** months of the April 13, 2005 mailing date of the Final Office Action to which it responds.

Respectfully submitted,



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Serial No. 09/596,362
Reply and Request for Reconsideration After Final
Honolulu, Hawaii, July 6, 2005

Dear Examiner Fubara,

As per our discussion regarding what makes my patent submission novel and new are two factors. The first is the use of kavapyrones to treat the craving of alcohol addiction and second factor is the administration of kavapyrones while the patient is continuing to consume alcohol.

My double blind study presented in the specification found that when kavapyrones are administered to patients addicted to and currently consuming alcohol there was a statistically significant percentage of patients achieving and maintaining sobriety over the control group.

The use of kavapyrones to reduce alcohol consumption was never previously reported. There is no report of kava or kavapyrones being used to treat alcohol craving or to achieve sobriety. The treatment of withdrawal symptoms is for the treatment of a patient who has ceased consuming alcohol and is suffering the consequences. The literature clearly distinguishes between dependence treatment, which is associated with why a patient cannot achieve sobriety, and withdrawal symptoms, which have nothing to do with assisting a patient in reaching sobriety. An alcoholic craves alcohol while consuming alcohol and therefore is driven to continue to drink. The alcoholic who is drinking has no withdrawal symptoms. It is the drinking alcoholic that my invention treats.

We have an endless array of medications to treat withdrawal symptoms but very few drugs have been shown to assist the alcoholic in achieving and maintaining sobriety as is reported in my specifications. In your office communication you state "The American Family Physician article provided by the applicant recognizes that treatment of withdrawal should be followed by the treatment of dependence". This is correct because they are two different entities and they must to be treated differently. But your statement also confirms the novel nature of my invention because I treat the dependence before withdrawal symptoms and while the patient is still consuming alcohol.

Also, the article is talking of forcibly preventing the alcoholic from drinking by confinement. Currently treating addiction by confinement and waiting for the cravings to naturally reduce is the way addicts are treated. The administration of kavapyrones to reduce craving while the patient is drinking is one aspect that makes my invention novel. My invention as established by my research is administered to an alcoholic while he is drinking and the alcoholic stops drinking because he no longer craves (desires) alcohol. My invention has shown that an alcoholic can carry on a normal life while being treated rather than being locked into a treatment center and forced into withdrawal.

Because we do not have effective treatments for the craving for alcohol, the state of the art is to forcibly withdraw alcohol and then attempt to treat the craving. Science will develop effective medications for craving and at that time addictions will no longer be the scourge on society it is today. My invention is an early step in a field that is just beginning to realize that someday we

will have effective medications for addiction that will not require extended stays in rehabilitation centers.

Cherksey has described a group of compounds that have a formula that excludes the kavapyrones. Cherksey repeatedly states that the group of compounds are for treating the symptoms of addiction and nicotine withdrawal. At no time does Cherksey discuss kavapyrones in relationship to addiction. Cherksey claims that kavapyrones are potassium channel activators but does not include the kavapyrones in his research regarding potassium channel activators. Cherksey claims kavapyrones are potassium channel activators but cites no references that establish this as factual. In a literature search of all published research at no time were the kavapyrones stated to be potassium channel activators.

When Umbdenstock discusses alcohol craving he specifies the formula he has devised for treating the craving of alcohol which never mentions kava. Umbdenstock teaches a nutritional formula designed to "resist the cravings that accompany withdrawal symptoms".

Thank you for your consideration.

Sincerely,

Greg Steiner